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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,134	11/26/2003	Katherine M. Burnett	054824-5001-02	4660

9629 7590 06/15/2005
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EXAMINER

MITCHELL, GREGORY W

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,134

Applicant(s)

BURNETT ET AL.

Examiner

Gregory W. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Amendments filed April 26, 2004. Claims 2-38 have been cancelled. Claim 1 is pending and is examined herein.

Priority

This Application is a continuation of US Application 09/562,376, filed May 01, 2000, which is a continuation-in-part of US Application 09/205,474, filed December 04, 1998.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Soudant et al. (USPN 5728393).

Soudant et al. discloses an anhydrous gel comprising absolute ethanol, hydroxyethyl cellulose, propylene glycol, polyethylene glycol, and N-oleoyldihydrosphingosine (medicament). See col. 8, lines 8-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (USPN 5993787).

Sun et al. teaches anhydrous topical preparations with good physical stability and excellent cosmetic attributes comprising (I) propylene carbonate, (II) one or more alcohols and/or glycols, including ethanol, isopropanol, propylene glycol, polyethylene glycol (PEG), etc., and (III) a therapeutically or cosmetically active ingredient (Abstract; col. 3, lines 13-32). Sun et al. discloses compositions, e.g. comprising miconazole (medicament), propylene carbonate, propylene glycol, ethanol, BHT, menthol and Klucel HF (col. 10, lines 32-40). Sun et al. does not specifically disclose an anhydrous composition wherein the specific alcohol/glycol combination as herein envisioned is exemplified.

It would have been obvious to one of ordinary skill in the art to prepare an anhydrous composition of Sun et al. comprising both, e.g., ethanol and PEG because (1) Sun et al. teaches, broadly, a genus of anhydrous topical compositions with components that fall within the scope of the instantly claimed composition; (2) Sun et al. teaches that one or more of the alcohols and/or glycols disclosed therein may be utilized in the anhydrous topical composition; (3) Sun et al. specifically exemplifies

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anhydrous topical compositions wherein multiple alcohols and/or glycols are disclosed; and (4) Sun et al. specifically discloses ethanol, isopropanol, propylene glycol, and polyethylene glycol as components useful therein. One would have been motivated to prepare an anhydrous topical composition comprising the components as herein envisioned because of an expectation of success in preparing a topical composition with good physical stability and excellent cosmetic attributes, as taught by Sun et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,238,683 ('683). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '683 patent claims an anhydrous composition comprising propylene glycol, PEG and glycerin, an anhydrous vehicle and medicaments comprising

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ketoconazole and desonide. Accordingly, claim 1 of '683 is within the scope of the instant claim 1.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 48 of copending Application No. 09/562,376 ('376). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '376 application claims an anhydrous composition comprising an anhydrous vehicle, propylene glycol, polyethylene glycol, glycerin and at least one azole antifungal agent (medicament). Accordingly, claim 48 of copending application '376 is within the scope of the instant claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

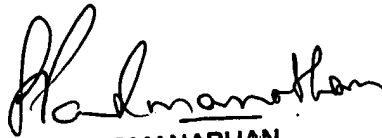
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER